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1: J Biol Response Mod. 1986 Jun;5(3):211-24.

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## Preparation and characterization of a polyvalent human melanoma antigen vaccine.

Bystryn JC, Jacobsen S, Harris M, Roses D, Speyer J, Levin M.

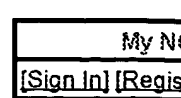
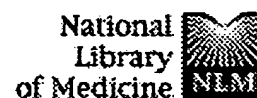
A polyvalent melanoma tumor antigen vaccine was prepared from antigens shed by a pool of human melanoma cells cultured in serum-free medium. The vaccine contained multiple melanoma associated antigens (MAAs) and was free of detectable fetal calf serum (FCS) proteins and Dr antigens. Three batches of vaccine prepared several months apart contained the same spectrum of tumor antigens. Thirteen patients with metastatic malignant melanomas were immunized intradermally with escalating doses of the vaccine in a Phase I study. There was no toxicity other than transient urticaria at the injection site. Humoral immunity, assayed by indirect immunoprecipitation, was augmented in five (38%) patients. Cellular immunity, assayed by delayed-type cutaneous hypersensitivity, was induced in four (31%) patients. Skin tests to a control vaccine prepared from pooled allogeneic lymphocytes were negative. Cutaneous metastases regressed completely in one patient who is now disease free after 2 years, and multiple cutaneous metastases have remained stable for 14 months in another patient. These results indicate that active immunization to a partially characterized polyvalent melanoma antigen vaccine is safe and can increase immunity to melanoma in some patients.

PMID: 3723138 [PubMed - indexed for MEDLINE]

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1: Cancer. 1988 Mar 15;61(6):1065-70.

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## Immunogenicity of a polyvalent melanoma antigen vaccine in humans.

Bystryn JC, Oratz R, Harris MN, Roses DE, Golomb FM, Speyer JL.

Department of Dermatology, Kaplan Cancer Center, New York, New York.

Fifty-five patients with Stage II (36 patients) or Stage III (19 patients) malignant melanoma confirmed histologically received adjuvant immunotherapy with a polyvalent melanoma antigen vaccine to evaluate toxicity and immunogenicity. There was no toxicity. Antibody and/or cellular immune responses to melanoma were induced more frequently in Stage II (36 patients [69%]) than Stage III (19 patients [53%]) disease. The ability of different immunization schedules, alum, or pretreatment with low-dose cyclophosphamide to potentiate immunogenicity was compared after 2 months of immunization. Immunization biweekly with a fixed intermediate dose of vaccine was more immunogenic than immunization weekly with escalating vaccine doses. Alum increased the intensity of cellular responses slightly, whereas pretreatment with cyclophosphamide augmented both the incidence and intensity of cellular immune responses slightly. However, these changes did not reach statistical significance. There was a reciprocal relationship between the induction of humoral and cellular immune responses. These results show that (1) active immunotherapy with a polyvalent melanoma vaccine is safe in patients with minimal disease, (2) the vaccine augments immunity to melanoma in many, but not all, patients, and (3) several immunization strategies failed to potentiate immunogenicity significantly.

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